UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	**MDL No. 1456**
	)	**Master File No. 01-12257-PBS**
	)	**Subcategory Case No. 06-11337**
	)	
	)	**Hon. Patti B. Saris**
THIS DOCUMENT RELATES TO:	)	
	)	
State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS	)	
	)	

DEFENDANT SANDOZ INC.'S BRIEF IN
SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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Pursuant to Pursuant to Rule 56(c) of the Federal Rules of Civil Procedure, Defendant Sandoz Inc. ("Sandoz"), by and through its attorneys of record, respectfully submits this Brief in Support of Its Motion for Summary Judgment.

INTRODUCTION

Sandoz joins and incorporates by reference Defendants' Joint Brief in Support of Their Motion for Partial Summary Judgment (hereinafter "Defendants' Joint Brief"). Sandoz submits this separate Motion based on facts unique to Sandoz. Specifically, Sandoz voluntarily provided to Medi-Cal, over a period of several years, its Average Manufacturer Price ("AMP") information for all drugs reimbursed by Medi-Cal during that period.[1] That is to say, from 1991 to 1997, Sandoz provided directly to Medi-Cal the AMP information for each and every Sandoz NDC. Thereafter, Medi-Cal received the Unit Rebate Amount ("URA") for all Sandoz drugs from CMS, and thus could—and on occasion did—quickly and easily calculate the related AMP. California simply cannot claim it was unable to discern the prices at which pharmacy providers actually acquired each of Sandoz' drugs at issue in this case, or could not understand and evaluate the "spreads" between AWP and net acquisition prices in the marketplace, because Sandoz gave California those very prices on an NDC by NDC basis. Indeed, when these facts are combined with the other undisputed facts regarding California's knowledge and understanding of generic drug pricing from, among other things, the 1995 OIG report prepared for California showing that generic drugs on average were purchased at 41% percent below AWP and the original Ven-A-Care complaint filed in July 1998, California certainly had a

[1] Federal law during the relevant time period defined AMPs as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade…." 42 U.S.C. § 1396r-8(k)(1). As further defined in the CMS drafted Rebate Agreement, AMP "includes cash discounts allowed and all other price reductions" to result in the fully discounted price received by the manufacturer. SOF at ¶ 6.

"perfect storm" of information regarding Sandoz pricing for years before this case was even filed.

These undisputed facts require summary judgment for two reasons. First, California cannot prove *scienter*, because it had full knowledge of all material facts as to Sandoz. Consequently, the claims must be dismissed in their entirety. Second, these facts show California's claims are barred in large measure by the statute of limitations. California indisputably knew the true state of affairs regarding Sandoz' prices starting in 1991, and received more and more information regarding Sandoz' prices and prices in the generic drug marketplace over time. The three year limitations period of the California False Claims Act, Cal. Gov't Code § 12650, *et seq.*, (the "CFCA") therefore applies and bars California from recovering on claims paid more than three years prior to the commencement of this action. Since Sandoz was not named as a defendant in this action until August of 2002, any CFCA claims California may have against Sandoz that accrued before August of 1999 are barred.[2]

ARGUMENT

I. CALIFORNIA'S CFCA CLAIMS AGAINST SANDOZ ARE INSUFFICIENT UNDER CONTROLLING CASE LAW

A. LEGAL STANDARD

The CFCA imposes liability on any person who: (1) knowingly presents or causes to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval; or (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision. Cal. Gov't Code § 12651 (1) - (2). Thus, a claim under the CFCA requires the

[2] California's First Amended Complaint in Intervention, dated August 25, 2005, alleges that the relevant time period for this action is January 1, 1994 to December 31, 2004.

plaintiff to prove the element of knowledge, or *scienter*. *See, e.g.*, *Thompson Pac. Constr., Inc. v. City of Sunnyvale***,** 155 Cal. App. 4th 525, 549 (Cal. Ct. App. 2007). To establish the *scienter* element of its CFCA claim, the State must prove that Sandoz "knowingly" or "intentionally" made a false statement or misrepresentation of a material fact or "knowingly" or "intentionally" concealed information. The federal False Claims Act ("FCA"), upon which the CFCA was modeled, treats "knowingly" in a similar manner, and cases interpreting the *scienter* requirement under the federal FCA are instructive in understanding the *scienter* requirements of the CFCA.[3]

In the federal FCA context, it is well-established that the element of *scienter* is vitiated where the government knows of the alleged fraud and nonetheless chooses to pay the claim. *See United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002) ("Today, we join with our sister circuits and hold that the government's knowledge of the facts underlying an allegedly false record or statement can negate the scienter required for an FCA violation. . . . [The government's] full knowledge of the material facts underlying any representations implicit in [the defendant's] conduct negates any knowledge that [the defendant] had regarding the truth or falsity of those representations."); *United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 544-45 (7th Cir. 1999) ("The government's prior knowledge of an allegedly false claim can vitiate a FCA action."); *United States ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321, 329 (9th Cir. 1995) (holding that the government's knowledge of the facts underlying an allegedly false record or statement can negate the *scienter* required for an FCA violation); *see also In re Pharmaceutical Industry Average Wholesale Price Litigation*, 245

[3] *See Am. Contract Servs. v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854, 860 (Cal. Ct. App. 2001) ("[T]he [California] False Claims Act is patterned largely on its federal counterpart and therefore federal decisions are persuasive on the meaning of the Act…") (internal citations omitted). California concedes that the CFCA and the FCA treat the knowledge requirement similarly. *See* Pl. State of California's Mem. of Law in Supp. of Mot. for Partial Summ. J. at 17.

F.R.D. 35, 41-42 (D. Mass. 2008) (holding that plaintiff's rejection of government knowledge as a defense to the FCA during a discovery dispute was "premature," given the possibility that such knowledge could vitiate *scienter*).

Similarly, in an action under the CFCA, the government's "knowledge [of a fraud] effectively negates the fraud or falsity required by the [CFCA]." *Am. Contract Servs. v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854, 864 (2001); *see also United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 n.8 (5th Cir. 2003) ("Inevitably, the extent of the government's knowledge is also bound up with whether the claim itself was false."). Likewise, "government knowledge" vitiates the requisite *scienter* under the CFCA: "there cannot be a knowing presentation of a false claim for payment where the government is fully aware of the facts surrounding the claim and approves it." *United States v. Shasta Servs. Inc.*, 440 F. Supp. 2d 1108, 1113 (E.D. Cal. 2006). Thus, if California knew of the allegedly "false" nature of Defendants' published AWPs but continued to use them to pay reimbursement claims, the claims at issue could not have been "false" nor could Defendants have knowingly caused the submission of "false" claims.

This is particularly true where a defendant itself has informed the government of the very facts on which the government claims to have been defrauded. *See, e.g., Massachusetts v. Mylan Labs*, 608 F. Supp. 2d 127, 149 (D. Mass. 2008) ("a defendant's disclosure ... to the government is relevant…because evidence of disclosure may point persuasively away from any conclusion that the defendant made a knowing misrepresentation. In other words, disclosure may establish that the defendant did not 'knowingly' submit false claims") (Saris, J.) (quoting *United States v. Newport News Shipbuilding Inc.*, 276 F. Supp. 2d 539, 564 (E.D. Va. 2003)); *see also United States ex rel. Costner*, 317 F.3d 883, 887-88 (8th Cir. 2003) ("A contractor that is open with the

government regarding problems and limitations and engages in a cooperative effort with the government to find a solution lacks the intent required by the [FCA].”); *Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412,1421 (9th Cir. 1992) (“The fact that the government knew of [defendant’s] mistakes and limitations, and that [defendant] was open with the government about them, suggests that while [defendant] might have been groping for solutions, it was not cheating the government in the effort.”).

B. SANDOZ DID NOT ACT WITH *SCIENTER* AS REQUIRED BY THE CALIFORNIA FALSE CLAIMS ACT

The undisputed facts in this case show that Sandoz’ acted without the *scienter* required for a CFCA claim because it provided average price information to Medi-Cal directly and indirectly throughout the entire time period at issue in this case. This “full knowledge of the material facts” regarding Sandoz’ AWPs, i.e., that they at times greatly exceeded average actual acquisition costs for retail pharmacy providers, was “‘so extensive that [Sandoz] could not as a matter of law possess the requisite state of mind to be liable under the FCA.’” *Mylan Labs.*, 608 F. Supp. 2d at 149 (quoting *Shaw v. AAA Eng’g & Drafting, Inc., 213 F.3d 519, 534* (10th Cir. 2000)).

Over a period of more than six years, from 1991 through 1997, Sandoz voluntarily provided its AMP data to Medi-Cal, on a quarterly basis, for each and every Sandoz drug reimbursed by the California Medicaid program. *See* Local Rule 56.1 Statement of Undisputed Material Facts in Support of Defendant Sandoz Inc.’s Motion for Summary Judgment (“SOF”) at ¶ 12. Although federal law only required Sandoz to provide its AMP data to HCFA during that time period, Sandoz separately provided that data to Medi-Cal. AMPs are important sources of information because they are based on actual transaction data and represent a statutorily defined measure of average prices obtained by Sandoz for drugs distributed to the retail pharmacy class

of trade. In short, AMPs are essentially what California claims AWPs should have been. *See* SOF at ¶ 7; Declaration of Catherine R. Castaldo ("Castaldo Decl.") Ex. B. (Transcript of Deposition of Mike Namba ("Namba Tr."), 150:5 – 10, Apr. 23, 2009)

> Q: Now, have – would you agree that Average Manufacturer Price more closely approximates Average Acquisition Cost as compared to AWP?
> A: I believe so.

Specifically, federal law during the relevant time period defined AMPs as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade…." 42 U.S.C. § 1396r-8(k)(1). This is further refined by the CMS drafted federal rebate agreement, which was the form contract each manufacturer (including Sandoz) was required to sign in order to have its drug eligible for Medicaid reimbursement, providing further explanation of the AMP calculation and directed that AMPs be reported to CMS "not later than 30 days after the last day of each rebate period under the agreement." 42 U.S.C. § 1396r-8(b)(3)(A)(i). The rebate agreement defined "wholesalers" to include "retailers." The AMP calculation thus represented the fully-discounted prices received by Sandoz for drugs sold directly or indirectly to retail pharmacies. As defined in the Rebate Agreement, AMP "includes cash discounts allowed *and all other price reductions*" (emphasis added). SOF at ¶ 6. *See also* 42 U.S.C. § 1396r-8(k)(1). Medi-Cal consequently had Sandoz net pricing information for drugs sold to retail pharmacies on a quarterly basis from 1991 to 1997, and cannot claim it did not understand on a specific and detailed level the relationship between Sandoz' AWP and average retail prices, and certainly cannot claim it is owed any damages through 1997.

Furthermore, even though Sandoz stopped directly providing AMP data to California at the end of 1997, California was able to calculate the AMPs for Sandoz' drugs throughout the

relevant time period. *See* SOF at ¶¶ 9 - 10. This is because California was able to calculate a given AMP based on the URA provided to it by CMS, which received Sandoz' AMP data directly from Sandoz pursuant to Sandoz' obligations under the Omnibus Budget Reconciliation Act of 1990. *See* SOF at ¶ 8. The URA for generic drugs is 11% of AMP. CMS provided all the URAs for every Sandoz drug. California then calculated the rebate due to it for each Sandoz drug by multiplying the URA by units reimbursed. In order to calculate the AMP for each Sandoz drug, California simply had to divide the URA by .11. CMS and Medi-Cal officials testified that the derivation of AMP from URA was a simple calculation. *See* SOF at ¶ 9 - 10; Castaldo Decl. Ex. G. (Transcript of Deposition of Deidre Duzor ("Duzor Tr."), 679: 12-21, Mar. 26, 2008)

> Q: Okay. So if you had the URA and you divided by .11, that would tell you what the AMP is, right? A: Yes. The AMPs have been fairly transparent for generic drugs. Q. If you have the URA? A: Because – right, because of the simple formula."

Castaldo Decl. Ex. J. (Transcript of Deposition of Craig Miller ("Miller Tr."), 83:15 – 84:8 Sept. 24, 2008)

> Q: But that's something you could fairly -- at least for the noninnovator multiple source drugs we talked about a few minutes ago, that's something that if I -- if you wanted to you could figure that AMP number relatively simply; couldn't you? …
> A: Oh. Yes.
> Q: I mean you just do the math?
> A: Right.
> Q: You reverse that division –
> A: Right.
> Q: -- with a calculator, and you've got the AMP?
> A: Right.

By evaluating the URAs, the State of California was easily able to determine, and did determine, any given drug's AMP. *See* SOF at ¶ 11; Castaldo Decl. Ex. B. (Namba Tr. at 166:16 – 167:3)

> Q: Okay. But … you just noted that you could find – from the unit rebate amount you could – you could calculate the – what the AMP would be?
> A: For generic drugs.
> Q. For generic drugs right. And so you saw, when you calculated AMP for the generic drug, that it – it was a very low number; right?
> A: Correct.

These undisputed facts show that California received the actual prices at which Sandoz' drugs were available to retail pharmacies in the marketplace on a quarterly basis from 1991 onward.

The facts regarding Sandoz' AMPs thus are different than those presented to the Court in *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 152 (D. Mass. 2008), which presented a more narrow argument regarding government knowledge based on AMP/URA information. First, unlike the Massachusetts set of facts, California did have the AMP information sent directly from Sandoz for many years, so no "reverse engineering" was necessary. *See* SOF at ¶¶ 12 -13. Second, unlike Massachusetts, California could and did use URAs to calculate AMPs. *See* SOF at ¶¶ 9-11. Third, unlike Massachusetts, the Sandoz drugs are all generic pharmaceuticals (or, in the parlance of the federal rebate statute, "non-innovator multisource drugs") where the URA is always 11%, thus alleviating the ambiguity cited in the Massachusetts case for brand (i.e., innovator) pharmaceuticals where the URA is *at least* 15%. *See Mylan Labs.*, 608 F. Supp. 2d at 152.

Moreover, these facts regarding Sandoz also must be considered in the context of the wealth of information known to California regarding the generic drug marketplace in general and the pricing "spreads" in that marketplace between AWP and actual transaction prices. That information, describe in more detail in the Joint Motion, includes, *inter alia*, a 1996 OIG report prepared for California showing that generic drugs on average were purchased at approximately AWP-41%, and the original Ven-A-Care complaint filed in 1998 which described how published

prices for drugs, especially generic drugs, exceeded providers' acquisition costs and resulted in payments by Medi-Cal that substantially exceeded costs.

Armed with specific data regarding Sandoz' prices and substantial additional information regarding generic drug pricing and its relationship to AWP, California cannot claim that it did not have the ability or resources to determine the prices at which pharmacists acquired drugs in the marketplace, such that they had to rely on the published AWPs. Indeed, not only did California know that such actual market prices existed, but Sandoz provided them with these prices directly. Because the State at all times had full knowledge of the price at which Sandoz' drugs were actually available to pharmacists, as a result of the very information that Sandoz submitted to the State either directly or through CMS, California cannot now establish, as a matter of law, the Sandoz acted with the *scienter* required for a CFCA claim. *See., e.g., Mylan Labs.*, 608 F. Supp. 2d at 149 (noting that the fact "[t]hat the government knew of the defendant's mistakes and limitations, and that the defendant was open with the government about them, suggests that ... the defendant was not cheating the government....") (Saris, J.) (internal citations omitted); *United States ex. rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 289 (4th Cir. 2002); *X Corp. v. Doe*, 816 F. Supp. 1086, 1094 (E.D. Va. 1993) (finding that disclosure of information allegedly concealed by party "provide[d] persuasive evidence that [the party] did not 'knowingly' make a misrepresentation").[4]

II. CALIFORNIA'S CFCA CLAIMS AGAINST SANDOZ PRIOR TO AUGUST 1999 ARE BARRED BY THE STATUTE OF LIMITATIONS

California's CFCA claims are governed by a three year statute of limitations. Although Ven-A-Care did not add Sandoz to this case until August 2002, Plaintiffs seek damages starting in 1994, presumably on the theory that the ten year discovery rule applies as to the claims against

[4] These same facts also show falsity cannot be proven as to Sandoz.

Sandoz. Plaintiffs have it wrong. The three year limitations period applies, and all claims prior to August 1999 are barred.

Section 12654(a) of the California Government Code limits the period in which an action under the CFCA may be filed to three years from the date of discovery:

> A civil action under Section 12652 may not be filed more than three years after the date of discovery by the official of the state or political subdivision charged with responsibility to act in the circumstances or, in any event, no more than 10 years after the date on which the violation of Section 12651 is committed.

To constitute "discovery" under the statute, an official does not need to have actual knowledge of the alleged fraud, but can simply "know[] of facts which would lead a reasonably prudent person to suspect it." *Debro v. Los Angeles Raiders*, 92 Cal. App. 4th 940, 953, 112 Cal. Rptr. 2d 329, 339 (Cal. Ct. App. 2001). *See also Beal v. Reynolds*, No. RG03 79214, 2004 WL 5064143 (Cal. Super. Ct. Jan. 5, 2004) (holding that, consistent with numerous other California cases, discovery rule "include[s] a 'should have discovered' standard") (citing *Debro, supra*).

In *Debro*, the plaintiff alleged that monies received by the Los Angeles Raiders from the City of Oakland pursuant to a purported loan were in fact a payoff or gift in violation of the CFCA. 92 Cal. App. 4th at 948, 112 Cal. Rptr. 2d at 334. The court held that the responsible government officials were put on constructive notice of the alleged violation at the time they signed the agreement. *Id.* at 953-54, 112 Cal. Rptr. 2d at 339. Rejecting the plaintiff's argument that it was difficult to unearth the violation because the document was called a loan agreement, the court stated that "[i]t is not necessary that all the facts be discovered for the limitations period to commence," merely that they would have "put responsible government officials on notice to inquire about a possible false claim." *Id.* at 954-55, 112 Cal. Rptr. 2d at 340. Following a similar approach in another AWP case, this Court has explained that "[u]nder the discovery rule,

the question is when there was sufficient information such that a reasonable [third party payor] in the plaintiffs' position would have been on notice to investigate the possibility that AWP had become unhinged from acquisition costs causing plaintiffs to overpay for drugs." *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20, 78 (D. Mass. 2007).

Here, Plaintiffs' cannot take advantage of the ten year discovery rule because California had specific and detailed knowledge of Sandoz prices in particular and generic drug pricing in general. Those facts were more than sufficient to "put responsible government officials on notice to inquire about a possible false claim." *Debro*, 92 Cal. App. 4th at 954 - 55, 112 Cal. Rptr. 2d at 340.

- California was aware as early as 1986 that published AWPs were substantially higher than providers' costs to acquire drugs.[5]

- California was specifically aware of the difference between AWP and actual average transaction prices at the retail level for each and every Sandoz NDC from 1991 to 1997 and the URAs for each NDC at all other times.

- In May of 1996, HHS-OIG published the results of its 1994/1995 survey of pharmacy acquisition costs for Medi-Cal providers in a report entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services" (A-06-95-00062).[6] The report found that, on average, pharmacists' invoice prices for brand-name or single source drugs were 17.5 percent below published AWPs and that invoice prices for generic or multi-source drugs were 41.5 percent below AWP.[7] John Rodriguez, the Deputy Director for Medical Care Services at the California Department of Health Services ("DHS"), the California agency that administers the Medi-Cal program, confirmed receipt of the report, indicating his hope that the report would "substantiate DHS' position that current drug

[5] *See, e.g.*, State of California's Supplemental Responses to Defendants' First Set of Interrogatories dated August 21, 2008.

[6] Defendants' Joint Statement of Undisputed Material Facts in Support of Their Joint Motion for Partial Summary Judgment Summary Judgment ("Defs.' J. SOF) at ¶ 32.

[7] Defs.' J. SOF at ¶ 32.

ingredient cost reimbursement by the Medi-Cal program does not reflect actual purchasing activity of California pharmacies."[8]

- In July of 1998, the relator, Ven-A-Care of the Florida Keys, Inc. ("Relator") filed the original *qui tam* complaint in this action.[9] On the same day it filed the original *qui tam* complaint, the Relator served the California Attorney General's office with a copy of the complaint and a written disclosure of substantially all the material evidence and information in its possession, as required by California Government Code Section 12652(c)(3). Although Sandoz was not named, the complaint named 23 other drug manufacturers and laid out essentially the same fraudulent scheme that is alleged against Sandoz in the first amended *qui tam* complaint.[10] Moreover, the complaint listed catalog and contract prices that were available to the Relator for the 23 named defendants' drugs.[11]

These facts put California "on notice to investigate the possibility that AWP had become unhinged from acquisition costs causing [California] to overpay for drugs." *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d at 78. Accordingly, California cannot take advantage of the ten year discovery rule, and its claims are limited by the three-year statute of limitations, which bars all of California's CFCA claims against Sandoz that accrued prior to August 1999.

CONCLUSION

For the reasons set forth above, Sandoz respectfully requests that the Court grant this motion and enter judgment in favor of Sandoz.

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[8] Defs.' J. SOF at ¶ 32.

[9] Defs.' J. SOF at ¶ 60.

[10] Defs.' J. SOF at ¶ 60.

[11] Defs.' J. SOF at ¶ 60.

Dated: November 25, 2009
New York, NY

Respectfully submitted,

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/s/ Wayne A. Cross

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CERTIFICATION PURSUANT TO LOCAL RULE 7.1

Pursuant to Local Rule 7.1(a)(2), the undersigned certifies that I conferred with counsel for plaintiffs and was advised that plaintiffs do not consent to this motion.

/s/ Wayne A. Cross
Wayne A. Cross

CERTIFICATE OF SERVICE

I, Jacqueline L. Chung, hereby certify that on November 25, 2009, I have caused true and correct copies of the foregoing Defendant Sandoz' Inc.'s Motion for Summary Judgment to be served on all counsel of record by electronic service pursuant to the Case Management Order No. 2 entered in by Honorable Patti B. Saris in MDL 1456.

/s/ Jacqueline L. Chung
Jacqueline L. Chung